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Date of Deposit: **April 7, 2009**

Attorney Docket No.: 28069-503001US

**IN THE UNITED STATES PATENT AND TRADEMARK OFFICE**

APPLICANTS: Mishra

CONFIRMATION NO.: 7018

SERIAL NO.: 09/321,766

EXAMINER: Zohreh A. Fay

FILING DATE: May 28, 1999

ART UNIT: 1612

FOR: THERMOPROTECTED COMPOSITIONS AND PROCESS FOR TERMINAL STEAM  
STERILIZATION OF MICROPARTICLE PREPARATIONS

**Mail Stop RCE**

Commissioner for Patents

P.O. Box 1450

Alexandria, VA 22313-1450

**DECLARATION UNDER 37 CFR § 1.132 OF AWADHESH K. MISHRA**

I, Awadhesh K. Mishra of 25563 via Brava, Valencia, California, 91355, United States, declare and state:

1. I have read and understand the subject matter described and claimed in the instant application, United States Patent Application Serial No. 09/321,766 filed May 28, 1999 ("the '766 application"), entitled "Thermoprotected Compositions and Process for Terminal Steam Sterilization of Microparticle Preparations."

2. I have read and understand the Office Action mailed of October 7, 2008 and understand that claims 21-38, 40-46, 48-54, 56, 57 and 63 are rejected under 35 U.S.C. §103(a) as being unpatentable over U.S. Patent No. 5,858,410 ("Muller") in view of U.S. Patent No. 5,739,152 ("Andersson").

3. I am a co-inventor of the '766 application.

4. I make this Declaration to establish that Tween 80 and Pluronic F68 are examples of surfactants that require, during terminal steam sterilization, elevation of their cloud point

Mishra  
USSN: 09/321,766

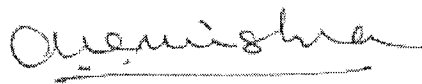
temperature by addition of a cloud point modifier, as well as being surfactants that coagulate upon steam sterilization.

5. I also wish to establish that the compositions of submicron- to micron-sized particulate suspension of water insoluble or poorly water-soluble pharmaceutical agents with only the addition of a phospholipid and thermoprotecting agent can be autoclaved without any marked increase in mean particle size.

6. I also state that the autoclavable compositions made up of the active substance, egg-phospholipid and tonicity agents, withstood stresses that are known by a person of ordinary skill in the art to promote particle size growth, flocculation, or agglomeration.

7. I further declare that the claimed compositions were successfully lyophilized before or after steam sterilization and the same preparations could be reconstituted by the addition of water to make an aqueous suspension having qualities similar to the original suspension.

8. I further declare that all statements made herein of my own knowledge are true and that all statements made on information and belief are believed to be true; and further that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under 18 U.S.C. § 1001 and that willful false statements may jeopardize the validity of this application and any patent issuing therefrom.



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Awadhesh K. Mishra

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April 02, 2009  
Date